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Electronic Health Record Certification in Oncology: Role of the Certification Commission for Health Information Technology

By Robert S. Miller, MD, FACP

Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins, Lutherville, MD

Introduction

Physicians have consistently cited upfront costs and uncertainties about potential system obsolescence as major barriers to the adoption of electronic health records (EHRs) in ambulatory settings.¹ Likewise, concerns about capital costs and return on investment were identified as impediments to EHR adoption by 74% and 32%, respectively, of acute care hospitals.² A fundamental deficiency that underlies many of these barriers, characteristic of a large number of EHRs currently marketed, is a lack of standards-based interoperability. This inability to exchange health information has historically deterred physicians from making the enormous investment often required to purchase and implement a clinical information system, particularly when they might feel such systems could limit future integration and expansion. Furthermore, small and medium-sized physician practices often lack the resources to engage consultants or to navigate a vendor-centric landscape of products on their own. Consequently, they perceive the risks of health information technology (HIT) purchase and implementation to be high, and until recent government incentive programs were introduced, they have shown considerable reluctance to make the leap from paper to digital records.

Origin and Structure of the Certification Commission for Health Information Technology

The HIT landscape in the United States began to change dramatically in 2004 with the creation of the Office of the National Coordinator for Health Information Technology (ONCHIT, often shortened to ONC), part of the US Department of Health and Human Services (HHS), and the appointment by President Bush of David Brailer, MD, PhD, as its head. On July 21, 2004, Brailer's office issued a *Framework for Strategic Action*,³

which listed four goals, each with a set of corresponding strategies, to enable the transformation of health care through the use of IT: (1) inform clinical practice, (2) interconnect clinicians, (3) personalize care, and (4) improve population health.³

One of the strategies under the "inform clinical practice" goal was "Reduce the risk of EHR investment."³⁽⁹⁾ One specific action envisioned was the creation of a private-sector certification process to "develop minimal product standards for EHR functionality, interoperability, and security."³⁽⁹⁾ From this *Framework for Strategic Action*, the Certification Commission for Health Information Technology (CCHIT) arose. CCHIT was founded as an independent, limited liability company (LLC) in 2004 through the sponsorship of three professional associations involved in HIT and health information management: the American Health Information Management Association, the Healthcare Information and Management Systems Society, and the National Alliance for Health Information Technology (an organization no longer in existence). The goal was to represent the interests of three key stakeholder groups: providers, HIT vendors and developers, and payers. Supplementary funding was provided in 2005 by additional sponsors, including the American Academy of Family Physicians, the American College of Physicians, and several corporate entities. In 2005, HHS contracted with CCHIT to develop the first EHR certification programs, and HHS officially recognized CCHIT as a certifying body in 2006. Under the terms of this government contract, CCHIT developed independent certification criteria for EHRs and began evaluating vendor products. The original LLC was dissolved in 2007, and the organization evolved to its present status as an independent nonprofit 501(c)3 corporation, registered in the state of Illinois and sustained by certification fees paid by vendors.⁴ Currently, its work is guided by two volunteer boards: a nine-person Board of

Trustees that has fiduciary responsibility and oversight of organizational strategy and a 19-person Board of Commissioners that oversees the primary activities of CCHIT staff and voluntary work groups in developing EHR certification criteria and testing processes for vendor products. The CCHIT commissioners represent a broad range of health care constituencies, including providers, academic institutions, government agencies, and IT vendors. No more than three of the 19 commissioners can be from the vendor community, per CCHIT by-laws.^{5,6}

CCHIT Mission and Scope in 2011

Despite its structural evolution, CCHIT's organizational mission, which is "accelerating the adoption of robust, interoperable health information technology (HIT) by creating a credible, efficient certification process," has remained unchanged.⁴ Likewise, its goals are similar to those proposed in the *Framework for Strategic Action*:

- Reduce the risks of investing in HIT
- Facilitate interoperability of HIT
- Unlock adoption incentives and regulatory relief
- Protect the privacy of health information. (Reber S, personal communication, April 4, 2011)

An independent and transparent EHR certification process enhances customer confidence and acts as a catalyst to spur adoption. Certification provides a necessary level of reassurance to the purchaser of an EHR system by minimizing some of the concerns about product reliability and interoperability. Small and medium-sized physician practices typically have few resources and little experience in evaluating complex electronic systems, particularly high-level functionality such as clinical decision support,⁷ and participation in a formal EHR certification mitigates the impact of some of these barriers. However, for a certification program to be successful and accepted in the marketplace, it must bring value not only to providers, but also to the other stakeholders, inclusive of vendors and health care purchasers/payers. The latter might stand to benefit the most from HIT but also might provide the financial incentives for adoption. The certification criteria and inspection process must balance the competing demands of the different stakeholders and must be perceived as suitably rigorous but fair.

The incentives for the adoption of EHRs in the United States were accelerated dramatically by the passage of the American Recovery and Reinvestment Act of 2009. The specific HIT components of the Act, referred to as the HITECH (Health Information Technology for Economic and Clinical Health) Act, authorized more than \$19 billion in federal incentives for physicians and hospitals to stimulate the implementation and meaningful use of certified EHRs.⁸ The nature of the certification process and the identity of the certifying body or bodies were not specified in the HITECH Act but were developed over the course of the subsequent 18 to 24 months. The publication of the Final Rule on the Stage 1 Meaningful Use guidelines by the Centers for Medicare and Medicaid Services⁹ in July 2010 clarified the requirements of the federal incentive program for EHRs, and the specifics of the permanent, federally defined HIT certification process were published by HHS in January

2011,¹⁰ superseding a previously defined temporary process. Full implementation of the permanent certification process is expected to be complete by January 1, 2012. To date, six organizations have been designated by ONCHIT as ONC-Authorized Testing and Certification Bodies (ONC-ATCBs) under the temporary process in place in 2011, to test and certify EHRs for compliance with the standards and certification criteria defined by HHS in the 2010 Final Rule.¹¹ These are: (1) SureScripts LLC, Arlington, VA (date of authorization: December 23, 2010; scope of authorization: EHR modules: e-prescribing, privacy, and security); (2) ICSA Labs, Mechanicsburg, PA (date of authorization: December 10, 2010; scope of authorization: complete EHR and EHR modules); (3) SLI Global Solutions, Denver, CO (date of authorization: December 10, 2010; scope of authorization: complete EHR and EHR modules); (4) InfoGard Laboratories, San Luis Obispo, CA (date of authorization: September 24, 2010; scope of authorization: complete EHR and EHR modules); (5) CCHIT, Chicago, IL (date of authorization: September 3, 2010; scope of authorization: complete EHR and EHR modules); and (6) Drummond Group, Austin, TX (date of authorization: September 3, 2010; scope of authorization: complete EHR and EHR modules).¹²

It is important to note that CCHIT offers two distinct EHR certification programs: its older, independently developed program begun in 2006, currently called CCHIT Certified, and the newer ONC-ATCB program created in 2010 under HHS guidance to certify EHRs that eligible professionals and hospitals will use to obtain meaningful use incentive dollars. Products can receive certification in one or both of the programs. Among the important differences are that the CCHIT Certified program is voluntary and its testing criteria are created by experts with domain and specialty expertise, whereas ONC-ATCB certification is mandated by the federal government for those wishing to collect meaningful use incentive dollars, with criteria established in published government rules.¹³ A more detailed comparison can be found in Figure 1. Existing CCHIT Certified programs include Ambulatory EHR (with optional add-on certification for child health, cardiovascular medicine, behavioral health, and dermatology), Inpatient EHR, Emergency Department EHR, Behavioral Health EHR (standalone), Long-Term and Post-Acute Care EHR, and ePrescribing (standalone).¹⁴ Currently, 138 EHRs have achieved CCHIT Certified status, and 282 have been certified under the CCHIT ONC-ATCB program, with much overlap between the two.¹⁵

CCHIT Criteria Development: The Oncology Use Case for CCHIT Certification

In June 2010, CCHIT announced the selection of two new volunteer workgroups to develop certification and testing criteria for EHRs in oncology and women's health.¹⁶ The members were appointed by the Board of Commissioners after an open application process and represented a broad range of health care constituencies, including providers, hospitals, and HIT vendors. The 15-member Oncology Workgroup was tasked with developing certification criteria for an oncology EHR that would be an "add-on" for products already having achieved, or applying for, CCHIT

Program Comparisons

Nature of certification	Voluntary, robust	Mandatory for \$\$\$, to minimum government standards
Criteria and testing tool development	Volunteer subject matter experts	Federal government
Providers served	Many types of providers seeking greater assurance when investing in new EHRs; specialty options available	All Medicare and Medicaid eligible providers and hospitals seeking incentive payments
Technology certified	Comprehensive, integrated EHRs + use verification, usability rating (Amb.) and vendor characteristics	Broadest array of EHR technologies: complete EHR and EHR modules
Accountable to	Providers	Providers, payers & public
Goals	Assurance of functionality, interoperability, security; meet provider needs for transparency of product	Meaningful use (as defined by CMS) to improve outcomes of care, support health reform

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Figure 1. Detailed comparison between certification requirements of the Certification Commission on Health Information Technology (CCHIT) and Office of the National Coordinator-Authorized Testing and Certification Bodies (ONC-ATCB). “Mandatory for \$\$\$\$” indicates that certification is required for eligibility to receive federal incentive funds. Amb., ambulatory; CMS, Centers for Medicare & Medicaid Services; EHR, electronic health record. Copyright CCHIT; used with permission.

Ambulatory EHR certification. In the months following selection, the workgroup met semimonthly by conference call, culminating in the publication of the first draft of the certification criteria and test scripts in November 2010.¹⁷ These documents were open for public inspection on the CCHIT Web site for approximately 30 days, during which time multiple detailed comments were received from a variety of stakeholders and interested parties.

The criteria developed by the CCHIT Oncology Workgroup followed the same consensus-based iterative process used by other workgroups in the development of certification criteria for other domains. Before the start of the technical work of developing criteria, the Board of Commissioners performed an analysis to determine the market readiness for expanding EHR certification to the domain of oncology and the potential benefits to market stakeholders. Once the decision was made to proceed with specialty certification, the CCHIT Board of Trustees approved the business case for the new development, and the Commissioners further defined the scope of the proposed project.¹³ The workgroup then evaluated potential sources for the EHR technology criteria. Although the development of the criteria is not strictly evidence based, they must be highly credible to potential stakeholders and defensible through the testing process. Regulatory requirements for compliance, federal standards for interoperability and security, recommendations from professional societies, and other instances of best practices in oncology informatics were all considered.

The workgroup relied on three primary source documents for the majority of the final draft criteria: (1) the Clinical Oncology Requirements for the EHR (CORE) document, a 2009 collaboration between ASCO, the National Cancer Institute (NCI) Center for Biomedical Informatics and Information

Technology, and the National Community Cancer Centers Program, which attempted to codify the functionality, common data elements, and interoperability standards required by an oncology EHR¹⁸; (2) the HL-7 (Health Level 7) Ambulatory Oncology EHR Functional Profile¹⁹; and (3) the joint ASCO/Oncology Nursing Society statement of chemotherapy administration safety standards, published in *Journal of Clinical Oncology* in 2009.²⁰ The first of these, the ASCO/NCI CORE document, was the most heavily utilized. Other sources included the ASCO Chemotherapy Treatment Plan/Treatment Summary templates²¹ and existing CCHIT ambulatory or inpatient criteria.

The final version of the draft criteria for the CCHIT Certified 2011 Oncology EHR was released for public comment on November 15, 2010 and was composed of 67 different elements, including 20 “roadmap” elements proposed for future versions.²² The criteria were subdivided into functional categories, such as Pathology Information, Chemotherapy, Medication Management, and Therapy Management. A large number of the criteria dealt with the chemotherapy administration process in a medical oncology practice or clinic, with a strong emphasis on ensuring patient safety and minimizing the risks associated with chemotherapy prescribing, dose calculations, and delivery. Most of the criteria began with the phrase, “The system shall provide the ability to . . .,” usually followed by a functional element consistent with safe chemotherapy administration principles. That language was chosen specifically so that vendors would be mandated to include the specified functionality but individual practices would have the flexibility to choose which elements they wanted to use, even though their inclusion in the criteria made a strong statement about optimal safe practice. Representative examples include:

Draft 1.110 The system shall provide the ability to cap certain medications at a preset dosage at the level of the regimen template when the calculated dose would exceed the maximum allowable dose.

Draft 1.111: The system shall provide the ability to alert the user when a dose that exceeds the maximum recommended dose per regimen is entered. Such an alert may be configured in one of two ways: (1) A hard stop (ie, not able to be overridden by the user); (2) A user-overridable alert that, when overridden, requires the user to provide a reason.

Draft 1.117: The system shall be capable of designating explicit routes for medications and prohibit selection of other routes during the ordering process.

Draft 1.141: The system shall allow changes made in chemotherapy dosing to be carried forth into subsequent cycles.

In developing the criteria, the workgroup attempted to balance the ideal state of an electronic record largely consisting of discrete data elements with the practical reality that most data in the paper record exist as unstructured text. Structured data were required for criteria related to cancer staging and certain aspects of therapy management that could be more easily codified:

Draft 1.103: The system shall provide the ability to capture and display as structured data AJCC Stage, as well as anatomic and nonanatomic factors required for AJCC Staging based on the current staging manual.

Draft 1.130: The system shall provide the ability to capture and display the following information regarding treatment as structured data: (1) Reason for discontinuing therapy: (End of Planned Treatment; Toxicity; Tumor Progression) (2) Best response: (Adjuvant – not applicable; Complete Response, Partial Response, Stable Disease, Progressive Disease).

Other draft elements dealt with such subjects as displaying patient performance status using standardized scales such as Karnofsky or Eastern Cooperative Oncology Group (Draft 1.132); the generation of oncology-specific flowsheets (Draft 1.140); and the automated creation of a treatment summary document, consistent with ASCO specifications (Draft 1.146).²¹

In addition to the draft criteria, the workgroup also created a test script to be used in the actual testing of vendor products. The test script consists of a series of steps roughly simulating an actual patient encounter, in which the vendor must use the system to perform a designated testing procedure, based on one or more of the draft criteria, and an expected result, with only a binary outcome (pass or fail).²³ For example, the procedure for test step 1.07 is “Document that the patient has two separate breast tumors: one is 2.0 cm and the other is 0.5 cm.” The expected result is “The information specified is captured in a

free text field.” This test step is based on criteria element Draft 1.01: “The system shall provide the ability to capture and display disease-specific pathology information in a free text field.”

After the close of the public comment period for the draft criteria and test scripts in December 2010, the workgroup spent several months reviewing the comments and preparing a response document. Some of the criteria and script elements were modified on the basis of comments received. Pilot tests were performed to assess the validity of the individual steps in the test script using three volunteer vendors, and further modifications were made where necessary. The final oncology certification criteria and test scripts were published on the CCHIT Web site on May 17, 2011, and applications for certification opened June 2, 2011. Once a vendor submits an application, the actual certification of the EHR itself is performed by a panel of independent jurors via Web conferencing, with a proctor from CCHIT online during the test. Although all criteria and test scripts are publicly available far in advance of CCHIT certification testing, the process is rigorous, as it requires 100% compliance, that is, vendors must pass all of the steps in the test script and meet 100% of the final certification criteria. This provides assurance to the purchaser of a certified EHR product that all elements have been satisfied and avoids the uncertainty associated with a more subjective protocol.

The transparency and multidisciplinary nature of the CCHIT criteria development process ensure that certification is a meaningful and clinically relevant achievement for an EHR product. However, it remains to be seen to what extent federal incentives for meaningful use will dampen vendor and purchaser interest in a separate and voluntary EHR certification such as CCHIT Certified. It is highly likely that in 2011 to 2013, physicians in the United States will continue to demonstrate growing interest in using EHRs certified under the ONC-ATCB program, so as to qualify for the \$44,000 incentive payment to offset some of their capital investment. It will require market research and careful attention to trends to determine how much end users and health care payers/purchasers will value the independent assurance of functionality and interoperability associated with certification that exceeds the minimum requirements of ONC-ATCB. It seems reasonable to expect that the additional rigor that programs like CCHIT Certified provides will remain of value to the involved stakeholders beyond the limited 3- to 5-year scope of HITECH incentives and meaningful use.

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Corresponding author: Robert S. Miller, MD, FACP, Sidney Kimmel
 Comprehensive Cancer Center at Johns Hopkins, Green Spring Sta-

tion, 10753 Falls Rd, Pavilion II, Suite 415, Lutherville, MD 21093;
 e-mail: rmille98@jhmi.edu.

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Electronic Chemotherapy Order Entry: A Major Cancer Center's Implementation

By Nancy T. Sklarin, MD, MS, Svetlana Granovskiy, MS, Eileen M. O'Reilly, MD,
 and Andrew D. Zelenetz, MD, PhD

Memorial Hospital; Memorial Sloan-Kettering Cancer Center, New York; Weill Medical College of Cornell University, New York, NY

Abstract

Implementation of a computerized provider order entry system for complex chemotherapy regimens at a large cancer center required intense effort from a multidisciplinary team of clinical and systems experts with experience in all facets of the chemotherapy process. The online tools had to resemble the paper forms used at the time and

parallel the successful established process as well as add new functionality. Close collaboration between the institution and the vendor was necessary. This article summarizes the institutional efforts, challenges, and collaborative processes that facilitated universal chemotherapy computerized electronic order entry across multiple sites during a period of several years.